Oles patents, either separately or in any combination, do not teach, suggest, disclose, or make obvious the invention of the above-identified application, as defined in claims 21-27.

The Examiner's allegations in support of this rejection were:

> Van Gorp discloses a process wherein a mucosal protein hydrolysate is added to protein-containing food or feed. Van Gorp also discloses the preservation of the mucosa starting material using well known preservatives. See col.4, lines 17-34 and 45-50. Note specifically Van Gorp's disclosure of the suitability of a heating step in the preservation methods as recited in applicant's claim 24. Note further that because it contains the same material, mucosa, Van Gorp's preserved product would inherently have the same ash amount as recited in the claims.
>
> Van Gorp differs from the claims in that Van Gorp does not use the claimed peroxide or phosphoric acid as a preservative. However, each of Oles (see, e.g., abstract) and Balslev (see e.g., abstract) make it clear that both phosphoric acid and peroxide were well known preservatives in food and/or pharmaceutical applications. Thus, the claimed substitution of well known preservatives for those used in Van Gorp must be considered an obvious substitution of one known equivalent preservative for another. That is, because the artisan of ordinary skill at the time of applicant's invention would have had a reasonable expectation from Oles and Balslev would have functioned equivalently to the preservatives disclosed by Van Gorp, the artisan of ordinary skill would have been motivated to have substituted Ole's phosphoric acid and/or Balslev's peroxide for the preservatives disclosed by Van Gorp.
>
> Lastly, it is noted that Van Gorp does not disclose the bacterial count of the preserved mucosa product, as recited in applicant's claims 26 and 27. However, because the entire objective of adding preservatives according to Van Gorp's disclosure is the prevention of bacterial growth in the mucosa products, it is respectfully submitted that the determination of an acceptable degree of preservation as measured by bacterial contamination would have been a matter of routine optimization on the part of the artisan or ordinary skill, the degree of bacterial contamination clearly being a result-effective parameter optimized by adding more or less preservative. Thus, absent some demonstration of an unexpected result inhering from the claimed process, a holding of obviousness under §103(a) is clearly required.

Nonetheless, despite the Examiner's comments in support of this rejection, the fact remains that the Van Gorp, Balslev, and Oles patents, either separately or in any combination, do not teach, suggest, disclose, or make obvious the invention of the above-identified application, as defined in claims 21-27.

Claim 21 that the Examiner has rejected based upon this alleged combination of the Van Gorp, Balslev, and Oles patents read as follows:

> *21. A method for preserving mucosa tissue comprising mixing a quantity of mucosa tissue with a preserving agent selected from the group consisting of hydrogen peroxide and phosphoric acid to yield the preserved mucosa tissue.*

The Van Gorp patent discloses a method of preparing a protein hydrolysate from mucosa tissue, where the protein hydrolysate is allegedly lower in ash content than protein hydrolysates prepared by prior techniques. The Van Gorp process combines the raw material (i.e. mucosa) with an oxygen-scavenging stabilizer, such as sodium metabisulfate or calcium propionate, with the mucosa prior to enzymatically hydrolyzing the preserved mucosa. (Col. 4, lines 22-34 and 46-50). The Examiner, in his comments recited above, characterizes the oxygen-scavenging stabilizers of the Van Gorp patent as "well known preservatives," and goes on to at least implicitly allege that it would be obvious to substitute a second "well known preservative" of either the Balslev patent or the Oles patent for a first "well known preservative" of the Van Gorp patent. However, Applicants point out that those skilled in the art would not go around substituting the first "well known preservative" for the second another "well known preservative" in willy-nilly fashion, without considering other critical information, such as the compatibility of the second "well known preservative" to and in the process that employs the first "well known preservative." To act otherwise would be irresponsible.

Again, the Van Gorp process employs an oxygen-scavenging stabilizer, such as sodium metabisulfate or calcium propionate, to preserve mucosa prior to subsequent enzymatic hydrolysis of the preserved mucosa. The Van Gorp patent does not mention either the hydrogen peroxide or the phosphoric acid that are required in the alternative by claim 21. Therefore, in an attempt to fabricate a modified form of the Van Gorp process that employs hydrogen peroxide, the Examiner relies on the Balslev patent that does employ hydrogen peroxide as a preservative in an artificial saliva production process. Likewise, in an attempt to fabricate a modified form of the Van

Gorp process that employs phosphoric acid, the Examiner relies on the Oles patent that does employ phosphoric acid as a preservative in a salad dressing product. These attempts notwithstanding, the Van Gorp patent is the only one of the three patents cited by the Examiner that concerns mucosa tissue.

Applicants first note that the Van Gorp patent actually teaches away from the Examiner's suggested substitution of hydrogen peroxide in place of the oxygen-scavenging stabilizer of the Van Gorp process, such as sodium metabisulfate or calcium propionate. Van Gorp is charged with knowledge of the Balslev patent since the Balslev patent was published well prior to the October 30, 1992 filing date of the priority application underlying the Van Gorp patent. Specifically, the Balslev patent issued, on March 20, 1984. However, despite this knowledge of the hydrogen peroxide gained from the predecessor Balslev patent, Van Gorp et al. nevertheless chose not to list hydrogen peroxide for use in the process of the Van Gorp patent. Consequently, the Van Gorp patent actually teaches away from the Examiner's suggested substitution of hydrogen peroxide in place of the oxygen-scavenging stabilizer of the Van Gorp process.

One possible reason Van Gorp chose not to list hydrogen peroxide for use in the process of the Van Gorp patent is readily evident from a comparison of the Balslev patent and the Van Gorp patent. The Balslev patent incorporates hydrogen peroxide a couple of different times in the course of preparing the artificial saliva of the Balslev process. According to the Balslev patent, the hydrogen peroxide serves as an oxidizing bactericide. (Col. 6, lines 5-10). In addition to being "an efficient microbiocidal agent," hydrogen peroxide also is said to serve in the Balslev patent as "a means to eliminate mucine-decomposing enzymatic activity." (Col. 6, lines 10-12). Indeed, the Balslev patent actively employs hydrogen peroxide in the Balslev process for the stated purpose of destroying enzymatic activity. (Col. 11, lines 35-41).

This enzymatic activity destruction property that the Balslev patent attributes to hydrogen peroxide may explain why Van Gorp chose not to list hydrogen peroxide for use in the process of the Van Gorp patent. Specifically, after the oxygen-scavenging stabilizer, such as sodium metabisulfate or calcium propionate, is added to the mucosa, the preserved mucosa is subsequently subjected to enzymatic hydrolysis. (Examples 1-3 at Col. 6, line 58, through col 7, line 58; and col.

4, line 45, through col. 5, line 4). This appears to explain why Van Gorp chose not to list hydrogen peroxide for use in the process of the Van Gorp patent. Van Gorp, based on the teachings of the Balslev patent, was concerned that the hydrogen peroxide might or would destroy, or at least hinder, enzymatic activity following preservation of the mucosa with hydrogen peroxide. Thus, according to the combined teachings of the Balslev patent and the Van Gorp patent, hydrogen peroxide would not work in the process of the Van Gorp patent and therefore should, despite the Examiner's suggestion to the contrary, be excluded from the Balslev process. Instead, the Balslev patent and the Van Gorp patent collectively teach away from the Examiner's suggested substitution of hydrogen peroxide in place of the oxygen-scavenging stabilizer of the Van Gorp process.

As another approach, we consider the overall Van Gorp process. One important objective of the Van Gorp patent is ash content reduction in protein hydrolysate derived from the mucosa tissue, as compared to ash contents achievable by the prior art in protein hydrolysate derived from the mucosa tissue. (Col. 3, lines 47-62; and col. 5, lines 18-62). The Van Gorp patent relies on extensive purification steps, as opposed to preservative selection, to effect the ash content reduction. (Col. 5, lines 4-62). Neither the Van Gorp patent nor the Balslev patent teaches, suggests, or discloses that the choice of preservative has any influence on the ash percentage in the product. Thus, when seeking to reduce ash contents in protein hydrolysate derived from mucosa tissue, one important objective of the Van Gorp patent, one would not be motivated to substitute the hydrogen peroxide of the Balslev patent in place of the preservatives employed in the Van Gorp process. For this additional reason, it would not be obvious to undertake the Examiner's suggested substitution of hydrogen peroxide from the Balslev process in place of the oxygen-scavenging stabilizer of the Van Gorp process.

Finally, the Balslev process employs the hydrogen peroxide a couple of different ways in the course of preparing the artificial saliva of the Balslev process. First, the Balslev process adds hydrogen peroxide to a first mucine solution prior to spray drying of the first mucine solution. (Col. 11, lines 32-47). Then, after the spray dried mucine is redissolved in water with other components, additional hydrogen peroxide is added to this subsequent solution. (Col. 11, lin 48, through col. 12, line 9). On the other hand, in the Van Gorp process, the oxygen-scavenging stabilizer, such as

sodium metabisulfate or calcium propionate, is added to the mucosa only once - namely prior to enzymatic hydrolysis of the preserved mucosa. (Examples 1-3 at Col. 6, line 58, through col 7, line 58; and col. 4, line 45, through col. 5, line 4). Consequently, due to this disparity between the way hydrogen peroxide is employed in the Balslev patent versus the way the oxygen-scavenging stabilizer is employed in the Van Gorp process, the Balslev and Van Gorp patents, collectively, do not teach how or where to incorporate hydrogen peroxide in the Van Gorp process. Therefore, for yet this additional reason, it would not be obvious to undertake the Examiner's suggested substitution of hydrogen peroxide from the Balslev process into the Van Gorp process.

Next, with regard to the Oles patent, Applicants first note that the Van Gorp patent actually teaches away from the Examiner's suggested substitution of phosphoric acid in place of the oxygen-scavenging stabilizer of the Van Gorp process, such as sodium metabisulfate or calcium propionate. Van Gorp is charged with knowledge of the Oles patent since the Oles patent was published well prior to the October 30, 1992 filing date of the priority application underlying the Van Gorp patent. Specifically, the Oles patent issued, on March 20, 1979. However, despite this knowledge of the phosphoric acid gained from the predecessor Oles patent, Van Gorp et al. nevertheless chose not to list phosphoric acid for use in the process of the Van Gorp patent. Consequently, the Van Gorp patent actually teaches away from the Examiner's suggested substitution of phosphoric acid in place of the oxygen-scavenging stabilizer of the Van Gorp process.

Furthermore, the applications of the oxygen-scavenging stabilizer of the Van Gorp process and the phosphoric acid of the Oles process are very different from each other. In the Van Gorp process, the oxygen-scavenging stabilizer is added to a raw material - mucosa - that is thereafter further processed and ultimately enzymatically hydrolyzed. The Van Gorp patent discloses that the hydrolyzed material is then incorporated in pig feed. (Col. 8, lines 24-29). On the other hand, the Oles process produces human food, namely completed food products such as salad dressings and mayonnaise. (Col. 2, lines 40-51). Furthermore, after mixing the food product components, the mixture obtained by the Ole process was only minimally further processed - homogenization and/or emulsification. (Col. 5, line 9, through col. 6, line 5).

These vast differences in the stage at which the oxygen-scavenging stabilizer is incorporated in the Van Gorp process versus when the phosphoric acid is incorporated in the Oles process raise significant questions about the transferability of the phosphoric acid preservation approach to the Van Gorp process. The absence of answers in either the Van Gorp patent or the Oles patent regarding this transferability demonstrates the speculative nature of this transferability issue. In essence, the Examiner's alleged obviousness becomes an "obvious to try" scenario which highlights the lack of motivation to actually make the substitution the Examiner suggests. This lack of motivation is further highlighted the differentiation in Oles between "chemical food preservatives," such as the oxygen-scavenging stabilizer, of the Van Gorp process and the phosphoric acid and acetic acid of the Oles process, (Col. 1, lines 6-38).

Furthermore, the vast differences between the animal tissue (i.e. mucosa) of the Van Gorp process to which the oxygen-scavenging stabilizer is added versus the consumer food products (i.e. mayonnaise and salad dressings) in which the phosphoric acid is incorporated in the Oles process raise additional and significant questions about the transferability of the phosphoric acid preservation approach to the Van Gorp process. Here, the switch from human foods to swine feed is indeed a big switch. Patents that concern preparation of swine feed are typically not very instructive about preparation of human foods. Likewise, the mode of action of the oxygen-scavenging stabilizer in relation to stabilization of the animal tissue (i.e. mucosa) of the Van Gorp process may very well differ in respects from the mode of action of the phosphoric acid in relation to preservation of the finished human food products of the Oles patent. The absence of answers in either the Van Gorp patent or the Oles patent regarding these transferability issues further demonstrates the speculative nature of this transferability issue. In essence, the Examiner's alleged obviousness once again becomes an "obvious to try" scenario which highlights the lack of motivation to actually make the substitution the Examiner suggests.

As another approach, we again consider the overall Van Gorp process. One important objective of the Van Gorp patent is ash content reduction in protein hydrolysate derived from the mucosa tissue, as compared to ash contents achievable by the prior art in protein hydrolysate derived from the mucosa tissue. (Col. 3, lines 47-62; and col. 5, lines 18-62). The Van Gorp patent relies

on extensive purification steps, as opposed to preservative selection, to effect the ash content reduction. (Col. 5, lines 4-62). Neither the Van Gorp patent nor the Oles patent teaches, suggests, or discloses that the choice of preservative has any influence on the ash percentage in the product. Thus, when seeking to reduce ash contents in protein hydrolysate derived from mucosa tissue, one important objective of the Van Gorp patent, one would not be motivated to substitute the phosphoric acid and acetic acid combination of the Oles patent in place of the preservatives employed in the Van Gorp process. For this additional reason, it would not be obvious to undertake the Examiner's suggested substitution of phosphoric acid from the Balslev process in place of the oxygen-scavenging stabilizer of the Van Gorp process.

Finally, we again consider the language of claim 21. Claim 21 lists options for the preserving agent in a Markush listing. Phosphoric acid is included in the Markush listing of the preserving agent, while acetic acid is not included in the Markush listing of the preserving agent. According to claim, mixing of the mucosa tissue and preserving agent of the Markush listing yields the "preserved mucosa tissue." However, the Oles patent only discloses joint use of phosphoric acid and organic food acid (such as acetic acid) together as the preserving agent of the Oles process:

> The food compositions of the present invention contain a synergistic combination of acetic acid or other organic food acid and phosphoric acid.

(Col. 2, lines 31-33). Thus, rather than simply substituting phosphoric acid in place of the oxygen-scavenging stabilizer of the Van Gorp process per the Examiner, it would instead be necessary to substitute phosphoric acid and organic food acid (such as acetic acid) together in place of the oxygen-scavenging stabilizer of the Van Gorp process to remain consistent with the teachings of the Oles patent about common use of the phosphoric acid and organic food acid, even though the Oles patent and/or the Van Gorp patent do not actually teach substitution of phosphoric acid and/or organic food acid in place of the oxygen-scavenging stabilizer of the Van Gorp process. Nonetheless, if such a substitution of phosphoric acid and organic food acid in place of the oxygen-scavenging stabilizer of the Van Gorp process, the net result would not equal the invention of the above-identified application, as defined in claim 21, since claim 21 requires that the phosphoric acid,

rather than a combination of the phosphoric acid and organic acid, be sufficient to transform the "mucosa tissue" into the "preserved mucosa tissue."

Independent claim 21 is believed allowable. Likewise, claims 22-27 are also believed allowable, since claims 22-27 each depend from allowable claim 21. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 21-27 under 35 U.S.C. §103 based upon the Van Gorp, Balslev, and Oles patents and that claims 21-27 be allowed.

New claims 36-54

As indicated above, Applicant has added new claims 36-54. Support for new claims 36-54 is believed to exist in the above-identified application. Applicants respectfully request consideration and allowance of new claims 36-54.

CONCLUSION

Claims 21-27 and 36-54 are believed allowable. Therefore, Applicants respectfully request that the Examiner reconsider and allow claims 21-27 and respectfully request that the Examiner consider and allow new claims 36-54. The Examiner is invited to contact Applicants' below-named attorney to discuss any aspect of this application and advance this application to allowance.

Respectfully submitted,

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Date: April 11, 2002

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APPENDIX:
MARKED UP VERSION OF CLAIM AMENDMENTS

Claims 1-20 and 28-35 are canceled, and new claims 36-54 are added as follows:

--36. A method of treating mucosa tissue, the method comprising combining the mucosa tissue and a peroxide-containing compound to form an intermediate.--

--37. The method of claim 36, wherein the peroxide-containing compound is hydrogen peroxide.--

--38. The method of claim 36, wherein the concentration of the peroxide-containing compound in the intermediate is initially less than about 1% by weight, based upon the total weight of the mucosa tissue and the peroxide-containing compound being 100% by weight.--

--39. The method of claim 38, wherein the concentration of the peroxide-containing compound in the intermediate is initially less than about 0.5% by weight, based upon the total weight of the mucosa tissue and the peroxide-containing compound being 100% by weight.--

--40. The method of claim 36, the method further comprising mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product, the concentration of the peroxide-containing compound remaining in the mucosa product being less than about 0.04% by weight, based upon the total weight of the mucosa product being 100% by weight.--

--41. The method of claim 36, the method further comprising mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product, the concentration of the peroxide-containing compound remaining in the mucosa product being less than about 0.01% by weight, based upon the total weight of the mucosa product being 100% by weight.--

--42. The improvement of claim 36, the method further comprising mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product, the concentration of the peroxide-containing compound remaining in the mucosa product being undetectable when the concentration of the peroxide-containing compound remaining in the mucosa product is determined using $KMnO_4$ titration.--

--43. The method of claim 36, the method further comprising:
heating the mucosa tissue to a temperature in the range of about 50-105°C prior to combining the peroxide-containing compound and the mucosa tissue.--

--44. The method of claim 36, the method further comprising:
heating the mucosa tissue to a temperature in the range of about 65-75°C prior to combining the peroxide-containing compound and the mucosa tissue.--

--45. The method of claim 36 wherein the mucosa tissue comprises substantially non-hydrolyzed mucosa tissue.--

APPENDIX:
MARKED UP VERSION OF CLAIM AMENDMENTS

--46. The method of claim 45 wherein the intermediate is a treated mucosa product, the method further comprising hydrolyzing the treated mucosa product to form a hydrolyzed mucosa product.--

--47. The method of claim 46 wherein the hydrolyzed mucosa product comprises heparin, the method further comprising extracting heparin from the hydrolyzed mucosa product.--

--48. The method of claim 46, the method further comprising contacting the hydrolyzed mucosa product with a protein-containing material under conditions effective to hydrolyze at least some protein of the protein-containing material and thereby reduce enzymatic activity of the hydrolyzed mucosa product.--

--49. The method of claim 36 wherein the mucosa tissue comprises hydrolyzed mucosa tissue.--

--50. The method of claim 49, the method further comprising contacting the hydrolyzed mucosa tissue with a protein-containing material under conditions effective to hydrolyze at least some protein of the protein-containing material and thereby reducing enzymatic activity of the hydrolyzed mucosa tissue.--

--51. The method of claim 36 wherein the intermediate is a treated mucosa product, the treated mucosa product having an ash concentration of less than about 10% by weight, based upon the total weight of the treated mucosa product being 100% by weight.--

--52. The method of claim 51, wherein the treated mucosa product has an ash content of less than about 7% by weight, based upon the total weight of the treated mucosa product being 100% by weight.--

--53. A method of treating mucosa tissue, the method comprising adding phosphoric acid to the mucosa tissue to form an intermediate.--

--54. The method of claim 53 wherein the intermediate initially has a pH in the range of about 2-4 after the phosphoric acid is added to the mucosa tissue.--